UNITED STATES DISTRICT COURT
FOR THE
DISTRICT OF VERMONT

State of Vermont and Vermont Agency of Administration, Plaintiffs v. Tommy G. Thompson, in his official capacity as Secretary of the United States Department of Health and Human Services, and Lester M. Crawford, in his official capacity as Acting Commissioner of the United States Food and Drug Administration, Defendants	)	Civil Action No.

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiffs, the State of Vermont and the Vermont Agency of Administration, by and through Vermont Attorney General William H. Sorrell, hereby submit the following complaint for declaratory and injunctive relief pursuant to 28 U.S.C. §§ 2201-2202 and 5 U.S.C. §§ 701-706:

PRELIMINARY STATEMENT

1. The State of Vermont and its Agency of Administration, on their own behalf and on behalf of current and retired Vermont state employees and their dependents who receive health insurance benefits from the State of Vermont, bring this action to address the failure and refusal of the United States Department of Health and Human Services ("HHS") and Food and Drug Administration ("FDA") to authorize the importation of prescription

drugs from Canada under any circumstances for the use of current and retired Vermont state employees and their covered dependents.

2. The State of Vermont, through its Agency of Administration (hereinafter "Vermont"), provides health insurance benefits to approxim ately 21,000 current and retired state employees and their covered dependents. The benefits provided by Vermont include prescription drugs. Vermont pays a portion of the cost of prescription drugs and the covered state employees pay the remaining portion.

3. Some prescription drugs sold in Canada are significantly less expensive than the same drugs that are sold in the United States.

4. In 2003 Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act, Public Law No. 108-173 (hereinafter "MMA"). Section 1121 of the MMA amended the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., to require the Secretary of the Department of Health and Human Services to permit pharmacists and wholesalers to import prescription drugs from Canada subject to limited terms and conditions that safeguard the public health. *See id*. (codified at 21 U.S.C. § 384(b)). The MMA also granted waiver authority to the defendants, while at the same time requiring them to publish guidance describing the circumstances under which defendants will consistently grant waivers to allow importation of prescription drugs for personal use. *See id*. (codified at 21 U.S.C. § 384(j)).

5. Following the enactment of the MMA, Vermont petitioned the HHS and FDA to approve a program that would allow for importation of prescription drugs from Canada for use by current and retired state employees and their covered dependents and further requested the promulgation of regulations as directed in section 1121 of the MMA.

6. Despite explicit direction from the Congress in the MMA to promulgate regulations permitting importation of prescription drugs from Canada and guidance regarding waivers that would also allow importation, HHS and FDA denied Vermont's petition and have taken no action to promulgate regulations or issue any guidance regarding waivers.

7. In denying Vermont's petition, the defendants relied upon section 804(l)(1) of the Federal Food, Drug and Cosmetic Act, which was adopted along with the other provisions of section 1121 of the MMA and is codified at 21 U.S.C. § 384(l)(1). Defendants assert that the requirements set forth in section 1121 of the MMA are ineffective until the Secretary of HHS certifies to Congress that they will pose no additional risk to public health and safety.

8. Vermont brings this action to redress the HHS and FDA's arbitrary and capricious and otherwise unreasonable denial of Vermont's request. In addition, Vermont maintains that section 804(l)(1) of the Federal Food, Drug, and Cosmetic Act, on which the defendants rely, violates Article I, § 1 of the United States Constitution by improperly delegating legislative power to the Secretary of HHS, an official of the Executive Branch. Vermont seeks appropriate declaratory and injunctive relief to require prompt adoption of regulations and waiver guidance and appropriate consideration of Vermont's petition.

JURISDICTION AND VENUE

9. This court has original jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 in that this action arises under Article I, § 1 of the Constitution of the United States and statutes of the United States.

10. This cause of action is for declaratory and injunctive relief pursuant to 28 U.S.C. §§ 2201-2202, 5 U.S.C. §§ 701-706, and 21 C.F.R. § 10.45.

11. Venue in this judicial district is proper pursuant to 28 U.S.C. § 1391(e).

PARTIES

12. The plaintiff State of Vermont is a sovereign state and brings this action on behalf of itself and current and former Vermont state employees and their dependents who receive health insurance benefits from the State of Vermont.

13. The plaintiff Vermont Agency of Administration is an executive agency of the State of Vermont with offices in Montpelier, Vermont. The Vermont Agency of Administration is authorized under Vermont law to contract on behalf of the State of Vermont to secure group insurance benefits for Vermont state employees, including but not limited to health insurance. *See* 3 V.S.A. § 631. It brings this action on behalf of itself and current and retired Vermont state employees and their dependents who receive health insurance benefits from the State of Vermont.

14. The defendant Tommy G. Thompson is the Secretary of HHS. He is sued in his official capacity.

15. Defendant Tommy G. Thompson is responsible for the administration of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., and has been directed by Congress to establish regulations and waiver guidance to allow for the importation of prescription drugs from Canada.

16. The defendant Lester M. Crawford is the Acting Commissioner of the FDA, an executive agency within HHS. *See* 21 U.S.C. § 393.

FACTUAL ALLEGATIONS

17. In December of 2003 the Vermont Agency of Administration filed a petition with the FDA pursuant to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., and section 1121 of MMA (hereinafter "the Petition"). *See* Attachment 1.

18. The Petition requested that the FDA allow the Vermont State Employees Medical Benefit Plan ("SEMBP") to establish a progr am for the orderly importation from Canada of prescription medications for use by its members. *See* Attachment 1. The Petition cited the financial burden on the SEMBP and its members associated with high prescription drug prices in the United States and the availability of comparatively lower-priced prescription drugs in Canada.

19. Vermont stated in the Petition that as part of its program it would contract with service providers with knowledge regarding which prescription medications are sold in Canada and manufactured in FDA-approved facilities. Vermont further stated in the Petition its willingness to take other appropriate steps to safeguard the public health.

20. By decision dated August 4, 2004, defendants denied the State's petition. *See* Attachment 2.

21. On information and belief, defendants have not to date initiated any rulemaking or provided any waiver guidance permitting pharmacists, wholesalers or individuals to import any prescription drugs into the United States from Canada.

ADMINISTRATIVE PROCEDURE ACT CLAIM (5 U.S.C. §§ 701-706)

22. Plaintiffs incorporate by reference and restate the allegations in Paragraphs 1 through 21.

23. Defendants' denial of Vermont's Petition is contrary to the obligations imposed on the defendants under 21 U.S.C. § 384 and otherwise contrary to federal law.

24. Defendants failure to proceed with the promulgation of regulations and waiver guidance is contrary to the obligations imposed on the defendants under 21 U.S.C. § 384 and otherwise contrary to federal law.

25. To the extent that the Federal Food, Drug, and Cosmetic Act confers any discretion on the defendants, defendants' denial of Vermont's Petition and refusal to proceed with rulemaking and issuance of waiver guidance was arbitrary and capricious, an abuse of discretion, and otherwise contrary to federal law.

26. Plaintiffs are entitled to declaratory and injunctive relief.

UNITED STATES CONSTITUTION ARTICLE I, § 1

27. Plaintiffs incorporate by reference and restate the allegations in Paragraphs 1 through 26.

28. Section 804(l)(1) of the Federal Food, Drug, and Cosmetic Act (codified at 21 U.S.C. § 384(l)(1)) improperly delegates legislative power to the Executive Branch, contrary to Article I, § 1 of the United States Constitution.

29. Plaintiffs are entitled to a declaration that section 804(l)(1) is unconstitutional and, therefore, invalid.

WHEREFORE, the plaintiffs respectfully request that this court:

A. issue a declaratory judgment that defendants' denial of Vermont's Petition and refusal to proceed with promulgation of regulations and waiver guidance, as provided in 21 U.S.C. §§ 384(b) and (j), is arbitrary and capricious and an abuse of discretion, and contrary to federal law, including but not limited Article I, § 1 of the United States Constitution;

B. issue a declaratory judgment that 21 U.S.C. § 384(l)(1) violates Article I, § 1 of the United States Constitution by improperly delegating legislative power to the Executive Branch and, therefore, is invalid;

C. issue an injunctive order requiring the defendants to proceed forthwith to promulgate regulations and issue waiver guidance in accordance with 21 U.S.C. §§ 384(b) and (j);

D. issue an injunctive order requiring the defendants to reconsider Vermont's Petition forthwith and to issue a prompt determination that is fully consistent with the court's declarations; and,

E. grant such further relief as the court deems just.

Dated: August 19, 2004

STATE OF VERMONT
AGENCY OF ADMINISTRATION

WILLIAM H. SORRELL
ATTORNEY GENERAL

By: _____

Michael O. McShane
Assistant Attorney General
Office of the Attorney General
109 State Street
Montpelier, VT 05609-1001
(802) 828-5500

By: _____

Mark J. Di Stefano
Assistant Attorney General
Office of the Attorney General
109 State Street
Montpelier, VT 05609-1001
(802) 828-3176